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16, 2003
— 613 P

BRACCO DIAGNOSTICS INC.,

Plaintiff,

- against -

AMERSHAM HEALTH INC., AMERSHAM HEALTH AS and AMERSHAM plc,

Defendants.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CIVIL ACTION NO.
Civil 03-6025 (SRC)

COMPLAINT

Plaintiff Bracco Diagnositcs Inc. ("Bracco"), by its attorneys, Saiber, Schlesinger Satz & Goldstein, LLC and Kramer Levin Naftalis & Frankel LLP, for its Complaint alleges:

NATURE OF THIS ACTION

1. Bracco and its associated companies invent, develop, manufacture and distribute a variety of diagnostic contrast agents, including one, Isovue®, that is approved and marketed as an x-ray contrast agent. Bracco has filed this lawsuit against Amersham Health Inc., Amersham Health AS and Amersham plc (collectively "Amersham") to halt Amersham's false and misleading advertising and promotion for Amersham's Visipaque™ x-ray contrast agent, which directly competes with Bracco's product.

2. Both explicitly and impliedly, Amersham is characterizing Visipaque™ as an x-ray contrast agent that is superior to low osmolar contrast agents, which group includes Isovue®, in safety. Amersham is also positioning its Visipaque™ as safer than other contrast agents such as Isovue® for certain high risk patients, such as diabetic patients and patients with compromised kidneys.

3. These claims are false. There is no evidence that Visipaque™ is clearly superior to all low osmolar contrast agents in safety or that it is safer than other agents for certain high risk patients. Indeed, the Food & Drug Administration ("FDA") has already ordered Amersham to stop making similar claims, but Amersham has continued to communicate the same false message.

4. Amersham's false and misleading claims are contained in promotional materials that are being extensively disseminated in connection with the promotion of its product and are designed to persuade radiologists and other related professionals who prescribe, purchase, recommend or use x-ray contrast agents (collectively referred to as "Radiologists"), and patients who receive them, that Amersham's product is somehow safer than those made by its competitors, particularly Isovue®. These claims violate the federal Lanham Act, 15 U.S.C. § 1125(a) and the common law of unfair competition. To prevent immediate and irreparable injury to Bracco as well as to the patient population, Bracco seeks to enjoin Amersham from further publication and dissemination of its false, misleading and unfair advertising and promotion of Visipaque™, to require Amersham to disseminate corrective advertising, and to recover damages.

THE PARTIES, JURISDICTION AND VENUE

5. Plaintiff Bracco is a Delaware corporation with its principal place of business at 107 College Road East, Princeton, New Jersey 08543. Bracco markets ethical drugs

principally in the diagnostic contrast agent areas (e.g., x-ray, radiopharmaceuticals and magnetic resonance imaging).

6. On information and belief, defendant Amersham Health Inc. is a Delaware corporation having its principal place of business at 101 Carnegie Center, Princeton, New Jersey 08540. On information and belief, defendant Amersham Health AS is a Norwegian corporation having its principal place of business at P.O. Box 4220 Nydalen, Nycoveien 2, N-0401 Oslo, Norway. On information and belief, defendant Amersham plc is an English company having its principal place of business at Amersham Place, Little Chalfont, Buckinghamshire HP7 9NA, United Kingdom.

7. This action seeks to redress violations of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) and the common law of unfair competition. This Court has jurisdiction over the subject matter of this action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338(a) for its claims arising out of the violations of Section 43(a) of the Lanham Act, and pursuant to 28 U.S.C. §§ 1332, 1338(b) and 1367 for its claims arising out of the common law of unfair competition.

8. Venue is properly laid in this district pursuant to 28 U.S.C. § 1391.

BACKGROUND

9. X-ray contrast agents are prescribed to patients by radiologists to improve the image taken by x-ray apparatus and thereby improve the Radiologists' ability to analyze the image and derive diagnostic information.

10. Isovue® was developed by a company that was related to Bracco, Sintetica, in Italy. Isovue® is approved by the FDA and indicated for use as an x-ray contrast agent. It remains among the most widely prescribed x-ray contrast agents in the world.

11. Isovue® is in the class of x-ray contrast agents known as non-ionic x-ray contrast agents. Other members of the class include Optiray®, Ultravist® and Oxilan®, which are manufactured and distributed by other companies.

12. Over the past years, Bracco and others have conducted extensive clinical research concerning the safety and efficacy of Isovue®. E.g., Kay et al., JAMA 2003; 289:553-558; Rosovsky et al., Radiology, 1996; 200:119-122; Haight et al., Radiology, 2003; 226:399-404. Those studies have shown that Isovue® is a safe and effective x-ray contrast agent for use by patients, including diabetic and other high risk patients, when used properly.

13. Amersham's Visipaque™ was approved by the FDA for use as an x-ray contrast agent.

14. The results of a multi-centered study ("NEPHRIC study") comparing Amersham's Visipaque™ and Amersham's Omnipaque® x-ray contrast agents in diabetic patients were published in the February 6, 2003 issue of The New England Journal of Medicine ("Nephrotoxic Effects in High-Risk Patients Undergoing Angiography," N. Engl. J. Med., 2003, 348; 6:492-499). The study results as reported suggest differences between Visipaque™ and Omnipaque® with regard to renal toxicity in certain high-risk patients. Only Visipaque™ and Omnipaque®, which are both known as non-ionic x-ray contrast agents, were used in the study.

15. Other studies have compared Visipaque™ to other x-ray contrast agents, including other non-ionic x-ray contrast agents. However, there are no studies that, either taken alone or together, compare Amersham's Visipaque™ to all of the x-ray contrast agents on the market or even all of the non-ionic x-ray contrast agents on the market.

Amersham's False And Misleading Promotional Campaign

16. Notwithstanding this lack of comparative evidence that could distinguish Amersham's Visipaque™ from Bracco's Isovue® and other non-ionic x-ray contrast agents,

Amersham commenced an advertising and promotional campaign that promotes Visipaque™ as though it were in a different class from Isovue® and other non-ionic x-ray contrast agents and as though it were distinguished from and safer than Isovue® and other non-ionic x-ray contrast agents.

Amersham's False And Misleading Press Release Regarding The NEPHRIC Study

17. On the same day that the NEPHRIC Study results were reported in The New England Journal of Medicine, Amersham issued a press release stating:

> Patients with existing kidney problems and diabetes are at higher risk of developing further kidney damage from the contrast media, which are used in medical diagnostic procedures. The NEPHRIC results show that the use of Visipaque™ significantly reduced the risk, with patients given Visipaque™ being 11 times less likely to develop kidney damage than those administered a conventional non-ionic contrast medium.

18. In the same press release, Dan Peter, President of Amersham's Medical Imaging division, stated:

> The NEPHRIC data clearly demonstrates that "Visipaque" offers a significantly better renal safety profile than traditional low osmolar non-ionic contrast media in at-risk patients. These patients constitute an unnecessary proportion of those individuals undergoing contrast-enhanced x-ray procedures. We believe that the data strongly support Visipaque™ as the agent of choice for these patient groups.

Mr. Peter explicitly and implicitly attempted to falsely and misleadingly compare and differentiate Visipaque™ from other non-ionic contrast agents on the market, such as Isovue®, without any supporting evidence. There is no evidence that supports a comparison between Visipaque™ and "traditional low osmolar non-ionic contrast media," that Visipaque™ has a "significantly better renal safety profile," or to make Visipaque™ "the agent of choice for [at-risk] patient groups."

19. The same press release also contained a statement attributed to Professor Peter Aspelin, the study's lead investigator:

> The NEPHRIC Study demonstrated that we can have increased confidence in administering Visipaque™ to high-risk patients.

The statement is misleading and potentially dangerous to patients. While the NEPHRIC Study suggested that Visipaque™ may produce fewer adverse effects than Omnipaque® on the kidneys of certain diabetic patients undergoing angiographic procedures, Radiologists should be cautious when administering Visipaque™ or any other contrast agent in diabetic patients, in patients with pre-existing renal failure, as well as all other patients to ensure that all necessary and well known steps (such as adequate hydration of patients) are taken to minimize untoward side effects. Moreover, the NEPHRIC study did not show any data on other patients that are at higher than usual risk for adverse events following the injection of iodinated products like Visipaque™, such as patients with asthma, thyroid disorders, or cardiac disease. The statement disseminated by Amersham may erroneously induce doctors to believe that Visipaque™ will not cause harmful effects to high-risk patients, with the result that doctors may diminish their level of attention toward necessary precautions that should always be taken when administering iodinated contrast to patients.

Amersham's Other False and Misleading
Promotional Materials Regarding The NEPHRIC Study

20. Amersham is distributing false and misleading promotional materials concerning the NEPHRIC study to Radiologists. These materials repeat and attempt to reinforce the false and misleading statements made in the press release.

21. One such promotional material is entitled the "VISIPAQUE PROTOCOL" which Amersham distributed to Radiologists and which has been pasted on the bulletin board of at least one imaging center. The VISIPAQUE PROTOCOL states in part that:

> PATIENTS MEETING ANY OF THE ABOVE CONDITIONS [THAT MAKE THEM HIGH RISK] MUST RECEIVE VISIPAQUE FOR PROCEDURES UTILIZING CONTRAST MEDIA.

This "mandate" set forth in the VISIPAQUE PROTOCOL, that only Visipaque™ must be used with certain patients, is false and misleading and there is no evidence in support of requiring the use of Visipaque™ for any patient group as opposed to other non-ionic contrast agents such as Isovue®.

Amersham's False And Misleading Sales Person Promotions

22. Amersham's sales persons have been disseminating the false and misleading promotional materials identified above.

23. Amersham's sales persons have also been making false and misleading statements to Radiologists. At the July 11-13, 2003 Rocky Mountain Radiological Society meeting in Vail, Colorado, Amersham's sales person, Joseph Murray, stated to a group of Radiologists that:

> Visipaque™ is clearly superior to low osmolar contrast agents in renal safety."

There is no evidence to support this false, misleading and potentially dangerous statement.

24. At the same meeting, Mr. Murray also stated to a group of Radiologists:

> Why open yourself up to a lawsuit? Why compromise your patients' safety when you have a safe contrast agent, Visipaque™, for diabetic patients?

There is no evidence to support this false, misleading and potentially dangerous statement.

Amersham's False And Misleading Statements On Its Website

25. On information and belief, Amersham currently maintains a website directed to Radiologists concerning Visipaque™. See amershamhealth.com/products/visipaque.

26. On that website, Amersham states that:

> Compared to LOCM [which Amersham identifies as including Isovue®,] for instance, Visipaque has been shown to cause significantly less discomfort for patients. This means patients remain comfortable, calm and cooperative in a stressful situation. (references omitted).

There is no evidence to support Amersham's comparison and attempt to distinguish all LOCM (an acronym for low osmolar contrast medium), which group includes Isovue®, rendering this statement false and misleading.

27. Also on that website, Amersham presents pictures of red blood cells and shows deformity attributed to non-ionic LOCM and little to no deformity with Visipaque™. There is no evidence to support that all non-ionic LOCM will produce the same deformity or that Visipaque™ is in a separate class from all non-ionic LOCM regarding red blood cell deformity, making the presentation false, misleading and potentially dangerous.

28. Also on that website, Amersham states under a heading entitled "What is the physiological impact," that:

> [Visipaque]…offers significantly better comfort to the patient, and this is an important feature, especially in relatively risky procedures which are unpleasant for patients (reference omitted).

There is no evidence to support Amersham's comparison and attempt to distinguish Visipaque™ as in a separate class of x-ray contrast agents that produce less discomfort and are safer.

29. Also on that website, Amersham states in a section concerning "Renal tolerability" that:

> There are indications that [Visipaque™] may even be less nephrotoxic than LOCM. (references omitted).

There is no evidence to support Amersham's comparison and attempt to distinguish Visipaque™ from LOCM in general.

30. Also on that website, Amersham states under a heading entitled "Vascular Imaging" that:

> Visipaque causes significantly less discomfort and pain compared with other contrast medium. (references omitted).

There is no evidence so support Amersham's comparison and attempt to distinguish Visipaque™ from all "other contrast medium."

31. Also on nearly every page of that website, Amersham states that "The NEPHRIC Study concludes that:"

> ...the likelihood for high risk patients to develop contrast-media induced nephropathy appears to be significantly reduced when [Visipaque™]...is used rather than a low-osmolar non-ionic contrast medium.

There is no evidence to support Amersham's comparison and attempt to distinguish Visipaque™ from "low-osmolar non-ionic contrast medium."

32. Amersham also repeats on its website its advertising slogan for Visipaque™, "What makes it equal is what sets it apart." There is no evidence to support Amersham's slogan for Visipaque™ which compares it to and attempts to distinguish it from all other x-ray contrast medium.

Partial Summary Of Amersham's Violative Practices

33. Amersham's false and misleading promotion as set forth above explicitly and implicitly attempts to place Visipaque™ in a different class of competitive non-ionic contrast agents than other non-ionic contrast agents, such as Isovue®, without any evidence in support.

34. Amersham's false and misleading promotion as set forth above explicitly and implicitly attempts to make comparisons to and differentiate from other non-ionic agents, such as Isovue®, without any evidence in support.

35. Amersham's false and misleading promotion as set forth above explicitly and implicitly attempts to communicate that all non-ionic contrast agents, including Isovue®, will produce the same clinical results as Omnipaque® did in the NEPHRIC Study, without any evidence in support.

36. Amersham's false and misleading promotion as set forth above explicitly and implicitly attempts to communicate that Visipaque™ is risk-free in patients without any evidence in support.

37. Amersham's false and misleading promotion as set forth above are inconsistent with the FDA approved labeling for Visipaque™, which does not permit Amersham to make comparative claims regarding other x-ray contrast agents or to distinguish Visipaque™ from other x-ray contrast agents on the basis of safety.

Amersham's False And Misleading Promotional Campaign Is Willful And Reckless

38. Despite lacking evidence to support its false and misleading promotional activities, Amersham has continued its violative practices.

39. On August 11, 2003, Bracco sent a letter to Dan Peters, President of Amersham's Medical Diagnostics division, informing Amersham of its false and misleading promotional activities and the health risks they present to patients. Amersham has not responded to Bracco's letter and has continued its violative practices.

40. Bracco has sent additional letters to Amersham that identify Amersham's false and misleading promotional activities.

41. Indeed, Amersham has had a long history of having its relevant promotional practices reprimanded or questioned:

a. On March 25, 1996 and April 12, 1996 the FDA advised Amersham that the:

> use of promotional claims regarding superior comparative safety [with Visipaque™], such as preferred use with high-risk cardiovascular patients with significant reduction in pain, discomfort, and warmth, should be unacceptable because they were unsubstantiated claims and inconsistent with the approved product labeling.

b. On September 15,1996, the FDA sent Amersham a Notice-of-Violation letter to Amersham concerning Amersham's unsupported superiority claims for Visipaque™.

c. On July 23, 1998 and November 17, 2002, the FDA sent additional letters to Amersham regarding unsupported superiority claims for Visipaque™.

42. Amersham's continuing violative practices despite multiple notice and warnings are reckless and willful.

The Harm to Bracco and to the Public

43. Due primarily to the success of Isovue®, Bracco has over the past established itself as a leader in the x-ray contrast agent field. Bracco's products have achieved a reputation with Radiologists as safe and effective. Given Amersham's claim of safety superiority, Radiologists may feel they have a responsibility to switch their patients from Isovue® to Visipaque™. Amersham's false claims of proven superiority thus threaten to irreparably harm Bracco by eroding Bracco's and Isovue®'s sales, goodwill and physician, purchaser and consumer confidence.

44. Bracco has no adequate remedy at law.

45. Amersham's false and misleading promotional campaign for Visipaque™ also poses a public health risk. Contrary to its claims, Visipaque™ is not "clearly superior to

low osmolar contrast agents in renal safety" or more appropriate for diabetic patients. Because some patients are not appropriate candidates for x-ray contrast agents, some patients for whom such agents would not be the best choice may be prescribed Visipaque™ on the mistaken belief that it somehow reduces the risk of these health problems normally associated with other x-ray contrast agents. There are other patients which must be carefully monitored and for whom rigorous precautions must be taken. Based on these claims, the patients and Radiologists may have a false sense of safety even though the risks have not changed.

FIRST COUNT
(Violation of Section 43(a) of the Lanham Act)

46. Bracco repeats and realleges the allegations contained in paragraphs 1 through 45 of this Complaint.

47. The claims and comparisons made by Amersham are false and misleading and violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

48. Unless Amersham is enjoined by this Court and ordered to retract and correct these claims, its false and misleading advertising and promotional activities will cause Bracco to suffer a loss of consumer and physician confidence, sales, profits and goodwill and will irreparably injure Bracco.

SECOND COUNT
(Violation of N.J.S.A. 56:4-1, *et. seq.*)

49. Bracco repeats and realleges the allegations contained in paragraphs 1 through 45 of the Complaint.

50. The above-described acts violate N.J.S.A. 56:4-1, *et. seq.*

THIRD COUNT
(Violation of common law of unfair competition,
unfair sales practices and/or deceptive trade practices)

51. Bracco repeats and realleges the allegations contained in paragraphs 1 through 45 of the Complaint.

52. The above-described acts constitute unfair competition, unfair sales practices and deceptive trade practices under the common law of the State of New Jersey.

FOURTH COUNT
(Negligent Misrepresentations)

53. Bracco repeats and realleges the allegations contained in paragraphs 1 through 45 of the Complaint.

54. The above-described acts constitute negligent misrepresentations under the common law of the State of New Jersey.

55. Doctors and purchasers have relied upon said misrepresentations to their detriment and the detriment of plaintiff Bracco.

Wherefore, Bracco respectfully requests that the Court:

(i) issue a preliminary and permanent injunction ordering that Amersham, its agents, servants, employees, representatives, subsidiaries and affiliates refrain from directly or indirectly using in commerce or causing to be published or otherwise disseminated any promotional materials or activities containing any of the false and misleading claims described in the Complaint;

(ii) issue a preliminary and permanent injunction ordering that Amersham, its agents, servants, employees, representatives, subsidiaries and affiliates refrain from directly or indirectly using in commerce any claim, statement,

or comparison that (a) suggests that Visipaque™ is superior to non-ionic x-ray contrast agents in renal safety; (b) makes any claim that Visipaque™ is a safer x-ray contrast agent or more appropriate than other products in the marketplace, including Isovue®, for diabetic, renally impaired or any other patients; (c) suggests that all non-ionic x-ray contrast agents produce the same clinical results as Omnipaque®; (d) makes any claim for Visipaque™ that is inconsistent with its FDA approved labeling; or (e) makes any other false or misleading claims about Visipaque™ and/or Isovue®;

(iii) issue a preliminary and permanent injunction directing Amersham to place appropriate corrective advertisements, reasonably designed to reach all persons to whom the Amersham advertisements and oral communications were directly or indirectly disseminated, and retracting the false, misleading, and unfair claims contained in those advertisements and oral statements;

(iv) issue an order pursuant to 15 U.S.C. § 1116(a) directing Amersham to file with the Court and serve on Bracco, within 30 days after entry of the injunction, a report, in writing and under oath, setting forth in detail the manner and form in which Amersham has complied with the injunction;

(v) issue a declaration that this is an "exceptional case" due to the willful nature of Amersham's false and misleading promotion;

(vi) award Bracco:

(a) all of Amersham's profits, gains and advantages derived from Amersham's unlawful conduct, such damages to be trebled pursuant to 15 U.S.C. § 1117;

(b) all damages sustained by Bracco by reason of Amersham's unlawful conduct, including all expenditures required to correct the false, misleading, unfair, and disparaging descriptions and representations alleged herein, such damages to be trebled pursuant to 15 U.S.C. § 1117;

(c) exemplary and punitive damages as the Court finds appropriate to deter any future willful conduct; and

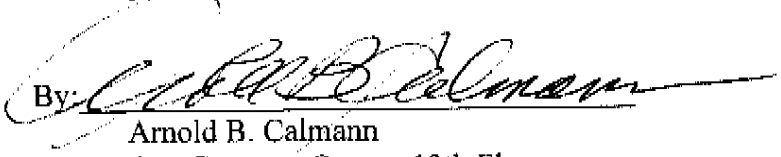
(d) interest on the foregoing sums;

(vii) award Bracco attorneys' fees and costs and disbursements of this action; and

(viii) grant such other and further relief as the Court deems just and proper.

Dated: December 16, 2003

SAIBER, SCHLESINGER SATZ & GOLDSTEIN, LLC
Attorneys for Plaintiff Bracco Diagnostics Inc.

By: 

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CERTIFICATION PURSUANT TO
LOCAL CIVIL RULE 11.2

I hereby certify that this matter is not the subject of any other action asserted by the plaintiffs herein, in any other action pending in any court or of any pending arbitration.

Arnold B. Calmann (AC-3245)

CERTIFICATION PURSUANT TO
LOCAL CIVIL RULE 201.1

I hereby certify that the within matter is not subject to compulsory arbitration because, *inter alia,* plaintiff seeks injunctive relief.

Arnold B. Calmann (AC-3245)

Dated: December 16, 2003